

The Objection to the Specification

The Examiner objects to the specification for the incorporation by reference to a publication of essential material. In particular, the Examiner cites the testing procedure outlined in the second complete paragraph on page 23 that "requires material from Larder which was not supplied to understand completely what testing was done." Applicants respectfully traverse the Examiner's rejection regarding this issue.

On page 23 of the present specification, Applicants described an *in vitro* test that was used to assess the ability of the claimed compounds to inhibit viral infection. Those experiments were performed in the MT-2 cell line, as was previously described by Larder, et al., *Antimicrobial Agents & Chemotherapy*, vol. 34, 436 (1990). A copy of that reference is enclosed for purposes of clarifying this issue for the Examiner. It is respectfully submitted that the specification properly describes the experiments conducted and one of ordinary skill in the art can readily duplicate the described experiment by simply following the description of the experiment as it appears in the specification with reference to Larder, et al., *supra*. That experiment is properly enabled. The experiment was presented to simply show anti-HIV activity. Applicants respectfully submit that the experiment on page 23 of the present specification has been properly described and with the presentation of the enclosed reference, further clarifies this issue for the Examiner. Applicants respectfully request the Examiner withdraw this objection to the specification and allow the present application to issue as a patent.

The §112, Second Paragraph Rejection of the Claims

The Examiner has rejected claims 12, 12, 18, 19, 26 and 27 as being indefinite for the reasons which are cited on page 4 of the office action. The Examiner queries "what are the drugs 'GW 420 867X' and 'Iopinavir'?" Both of these compounds, more correctly presented as GW420867X and Lopinavir, are known anti-HIV agents as previously explained. GW420867X is a quinoxaline non-nucleoside reverse transcriptase inhibitor of Glaxo-Wellcome, currently being used clinically in the treatment of HIV infections. A copy of Ismail, et al., *Xenobiotica*, 1999, vol. 29, no. 9, pp. 957-967, which describes urinary metabolites of this anti-HIV agent is enclosed. Note that the chemical structure for

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GW420867X is presented on page 958 of the text. Applicants also enclose a copy of a PUBMED search for this compound, further evidencing its use as a reverse transcriptase inhibitor of HIV.

Regarding Lopinavir, this compound is a protease inhibitor from Abbott Laboratories for use in the treatment of HIV. It's chemical structure can be seen in the attached paper, Ohtaka, et al., *Biochemistry*, 2003, 42, 13659-13666, on page 13661. It is a well-known anti-HIV agent.

It is respectfully submitted that with the amendment of the terms directed to the two compounds questioned by the Examiner, the claims now meet the requirements of 35 U.S.C. §112, second paragraph.

The §112. First Paragraph Rejection

The Examiner has rejected claims 7-8, 10 and 23-30 under 35 U.S.C. §112, first paragraph for the reasons which are set forth in paragraph 7 on pages 5-8 of the current office action. Applicants respectfully submit that the Examiner's rejection here has been rendered moot by the amendment to the present claims. The rejected claims have been cancelled without prejudice. Applicants will make a determination in the near future as to the advisability of refilling the cancelled claims in a continuation/divisional application to present data associate with those claims and seek their allowance.

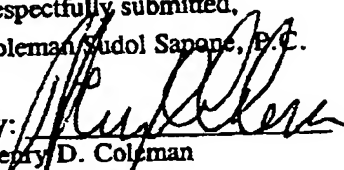
For the above reasons, Applicants respectfully assert that the claims set forth in the amendment to the application of the present invention are now in compliance with 35 U.S.C. Applicants respectfully submit that the present application is now in condition for allowance and such action is earnestly solicited. Applicants have cancelled 11 claims and have not added any claim to the present application.

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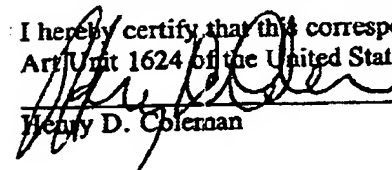
No fee is therefore due for the presentation of this amendment. If any fee is due, please charge/credit Deposit Account No. 04-0838.

Respectfully submitted,
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being sent to Examiner McKenzie in Group Art Unit 1624 of the United States Patent and Trademark Office on June 22, 2004.


Henry D. Coleman

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